intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, D.C. 20426, in accordance with the Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before January 12, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-34633 Filed 12-30-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-2064-000]

Donald B. Riefler; Application

December 28, 1983.

The filing individual submits the following:

Take notice that on December 20, 1983, Donald B. Riefler filed an application pursuant to section 305(b) of the Federal Power Act to hold the following positions:

Director—Niagara Mohawk Power Corporation
Director—Morgan Bank (Delaware)
Chairman, Sources and Uses of Funds Committee—Morgan Guaranty Trust Company of New York
Chairman, Sources and Uses of Funds Committee—J. P. Morgan & Company, Incorporated
Director—The National Reinsurance Corporation
Treasurer—J. P. Morgan Leasefunding Corporation
Treasurer—J. P. Morgan Interfunding Corporation
Director—Private Export Funding Corporation

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before January 17, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-34634 Filed 12-30-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-2063-000]

C. Larry Schmidt; Application

December 28, 1983.

The filing individual submits the following:

Take notice that on December 19, 1983, C. Larry Schmidt filed an application pursuant to section 305(b) of the Federal Power Act to hold the following positions:

Vice President—The Cincinnati Gas & Electric Company
Vice President Director—The Union Light, Heat and Power Company

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before January 17, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-34635 Filed 12-30-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ER82-708-000 and ER83-77-000]

West Texas Utilities Co.; Refund Report

December 28, 1983.

Take notice that on December 2, 1983 West Texas Utilities Company (West Texas) submitted for filing its Refund Report pursuant to an October 19, 1983 Commission Letter Order which accepted the settlement agreement reached by West Texas and its wholesale customers.

West Texas states that it refunded any amounts collected in excess of the settlement rates.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before January 11, 1984. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-34636 Filed 12-30-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ID-2062-000]

Franklin H. Williams; Application

December 28, 1983.

The filing individual submits the following:

Take notice that on December 9, 1983, Franklin H. Williams filed an application pursuant to section 305(b) of the Federal Power Act to hold the following positions:

Director—Consolidated Edison Company of New York, Inc.
Director—Chemical New York Corporation and Chemical Bank.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before January 12, 1984. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-34637 Filed 12-30-83; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS 42046; FRL 2466-7]

Cyclohexanone; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC) recommended to EPA

that cyclohexanone be considered for health and environmental effects testing. Following the recommendation, a group of U.S. cyclohexanone manufacturers submitted a proposed program on cyclohexanone for health effects testing. EPA has tentatively concluded that the industry testing proposal is adequate to address the ITC's and the Agency's testing concerns for health effects and that environmental effects testing for cyclohexanone is not necessary. Consequently, EPA is not at this time proposing a rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require health or environmental effects testing of cyclohexanone. This notice constitutes the Agency's response to the ITC's designation of cyclohexanone as required by section 4(e) of TSCA.

DATE: Interested persons are invited to comment on this proposed decision. All comments should be submitted on or before February 17, 1984.

ADDRESS: Written comments should bear the document control number [OPTS-42046] and should be submitted in triplicate to TSCA Public Information Officer (TS-793), Office of Pesticides and Toxic Substances, Rm E-108, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404). Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations to require manufacturers and processors to test particular chemical substances and mixtures. Data developed through these test programs are used by EPA in assessing the risks that the tested chemicals present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act.

In April, 1979, the ITC designated cyclohexanone for priority consideration in its Fourth Report, published in the Federal Register of June 1, 1979 (44 FR 31866) (Ref. 34). The ITC recommended that cyclohexanone be considered for (1) Health effects testing, including carcinogenicity, mutagenicity, teratogenicity (with behavioral studies in the offspring) and other chronic effects (including neurological and reproductive studies); (2) an epidemiological study; and (3) environmental effects testing. The ITC's recommendations for testing of cyclohexanone were based on: (1) substantial production, (2) its widespread use as an industrial solvent and as a solvent in consumer use products, which was expected to result in potentially high worker and general population exposure, and (3) potentially large quantities released to the environment.

In evaluating the ITC's testing recommendations for cyclohexanone, EPA considered all revelant information, including the following: (1) Information presented in the ITC's Fourth Report; (2) information reported by manufacturers of cyclohexanone, represented by the Industrial Health Foundation Cyclohexanone Study Group; (3) data submitted under TSCA sections 8(a) Preliminary Assessment Information Rule (40 CFR Part 712) and 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716); and (4) other published and unpublished data available to the Agency. Based on its evaluation, as discussed in Unit IV, EPA is not initiating rulemaking at this time under section 4(a) to require health or environmental effects testing of cyclohexanone.

II. Assessment of Exposure and Health and Environmental Effects

A. Production, Use, and Exposure

Cyclohexanone is a six carbon, saturated, cyclic ketone. The only functional group present is the carbonyl (C=O) group. It is a colorless liquid at room temperature (boiling point 156°C at 1 atm.) with an odor resembling peppermint and acetone (Ref. 24).

1. *Production.* Production of cyclohexanone in 1981 was reported to be 766 million pounds, most of which was used as a captive intermediate in the production of caprolactam and adipic acid, which in turn are intermediates for nylon 6 and nylon 6,6, respectively. Merchant sales of cyclohexanone were 4.7 percent (36 million pounds) of the 1981 production total (Ref. 36).

Cyclohexanone has uses as a chemical intermediate and as a solvent for resins, lacquers, dyes, and insecticides (Ref. 26). Cyclohexanone is sold in various grades, including a commercial grade (99 percent ketone) and a high purity grade (99.8 percent ketone, Ref. 26).

Cyclohexanone's slow evaporation rate and good solvency make it an attractive solvent in coatings where a slower drying rate is desirable. It is an excellent solvent for various protective coatings and adhesives, for vinyl chloride and copolymer resins, and is also used as an ingredient in some pesticide formulations (Ref. 33). Because of its expense relative to other solvents (such as acetone and methyl ethyl ketone) and because of undependable supplies during a tight (1973) market, growth of cyclohexanone as a solvent has not occurred as one might have expected (Ref. 32). Of the ketone solvents, cyclohexanone comprises about three percent of the market; only about four to five percent of total cyclohexanone production is used as a solvent (Refs. 4 and 43).

2. *Occupational exposure.* The number of persons exposed to cyclohexanone in its use as a chemical intermediate is limited because nylon manufacturing is done in an automated, closed system. Exposure in these operations could occur during cleaning operations or from accidental spills. Humans are likely to be exposed to cyclohexanone when it is used as a solvent in open processes. The National Institute for Occupational Safety and Health (NIOSH) surveyed three industrial sites where cyclohexanone was known to be used as a solvent. Concentrations of cyclohexanone in atmospheric samples varied from < 1 ppm to 21 ppm, depending on the operation (Ref. 38). The American Conference of Governmental Industrial Hygienists (ACGIH) has a recommended standard (8-hour time-weighted average) of 50 ppm in air for cyclohexanone in the workplace. ACGIH is planning on lowering its recommendation to 25 ppm, based on a NIOSH (1978) proposal (Ref. 1). According to NIOSH (1980) estimates, 559,200 people are potentially exposed to cyclohexanone in the workplace.

3. *Consumer exposure.* Even in its solvent uses, cyclohexanone is used more frequently in industrial rather than consumer applications. Lee *et al.* (1979) reported, however, that cyclohexanone is used as a solvent in consumer products such as spot removers for leathers and textiles, metal degreasers, lacquers and stains, and paint removers used in furniture repairing and refinishing. Exposure from these uses could occur through inhalation or through skin absorption.

4. *General population exposure.* Patterson *et al.* (1976) modelled the release of cyclohexanone from a major manufacturing plant. They assumed a

plant production of 240 million pounds/year and an emission rate of one percent of that, or 34.5 g/sec of cyclohexanone. This latter estimate was derived from information on similar chemical processes (Ref. 40). They calculated that ground level concentrations, 500 meters from the release source, could average 1.3 ppm over a 1-hour time period or approximately 1.0 ppm over a 24-hour time period. Aside from this postulated exposure from cyclohexanone in the atmosphere in vicinities very close to industrial plants, there is little indication of general population exposure. However, Shackleford and Keith (1976) reported the presence of cyclohexanone in four samples of finished drinking water analyzed by the EPA Laboratory in Cincinnati, Ohio and in one sample of drinking water analyzed in Ottumwa, Iowa. Sampling sites and concentration levels were not given.

5. *Release.* Releases of cyclohexanone into the environment are expected to be largely due to atmospheric releases resulting from production, storage, and (especially) solvent use of the chemical substance (Ref. 40). Patterson *et al.* (1976) estimated annual losses of cyclohexanone in 1974 (production about 550 million pounds) of 42.8 million pounds from solvent use, 8.5 million pounds from production losses and 0.3 million pounds from storage losses. They assumed that all of this loss would be to the atmosphere and, in the case of the solvent loss, would be widely scattered geographically. Using some other assumptions, JRB (1981) estimated annual releases of cyclohexanone to the environment for 1979 (production 875 million pounds); again it was estimated that the single greatest release of cyclohexanone into the environment would occur from solvent loss to the atmosphere (43.6 million pounds). Production losses would contribute an additional 4.85 million pounds to the atmosphere and 20.3 million pounds to wastewater. Losses from other processes would account for an additional 0.35 million pounds to air and 0.055 million pounds to wastewater.

The greatest point source of cyclohexanone release to surface waters would be from wastewater discharge (Ref. 24). Modelling was performed for this source using worst case assumptions, including saturated influent (25,000 ppm cyclohexanone) and no waste treatment (Ref. 57). Maximum environmental concentrations of less than 1 ppb up to 60 ppm, varying according to the particular receiving stream, were calculated for each of the seven plants manufacturing cyclohexanone in the United States. Mean environmental levels were estimated to be less than 1 ppb up to 8.23 ppm cyclohexanone, depending on the site (Ref. 57). However, cyclohexanone is treated before being discharged and available information indicates that environmental levels of cyclohexanone, which would occur as a result of wastewater discharge, are four to six orders of magnitude lower than the worst-case estimates just given (i.e., maximum aquatic concentrations would be less than 6 ppb after treatment). It was reported that four of the six cyclohexanone producers discharge to wastewater treatment plants that utilize activated sludge systems. A fifth producer has two sites, one which also discharges to an activated sludge treatment plant. The second site discharges to a retention basin only. However, analysis of the effluent from the retention basin has shown no detectable cyclohexanone (detection limit 1 mg/l). The sixth producer's wastewater containing cyclohexanone is disposed of in injection wells (Ref. 21).

It was further reported that there is little information available at the present time on actual influent and effluent concentrations of cyclohexanone in wastewater. However, limited data suggest that concentrations vary from 1–100 mg/l in the influent to the activated sludge treatment plants. One in-house treatability study of cyclohexanone, utilizing a scale model of an activated sludge plant, showed reductions greater than 99 percent (Ref. 21). Furthermore, process wastes containing cyclohexanone are regulated under RCRA. Spent cyclohexanone solvent and the still bottoms from the spent solvent recovery are hazardous wastes listed under 40 CFR § 261.31 as EPA Hazardous Waste No. F003.

B. Health Effects Information

1. *Metabolism.* Cyclohexanone is quickly metabolized and excreted with the major metabolic pathway being transformation to cyclohexanol followed by glucuronidation in the liver with subsequent excretion of the glucuronic acid conjugates in the bile and urine (Refs. 14, 23, 29, 52, and 53).

2. *Acute Toxicity.* Acute LD_{50} studies on guinea pigs, rats, mice and rabbits show that the acute toxicity of cyclohexanone to these species is on the order of 1,000 to 2,000 mg/kg (oral or intravenous routes of administration); no significant difference in acute toxicity was found between males and females (Refs. 19, 52 and 53).

Exposure by inhalation killed two of four rabbits exposed for 90 hours at 3,082 ppm (Ref. 53). Although there were signs of toxicity observed, no fatalities were observed among the four animals treated at the next highest dose in this experiment, 1,414 ppm, after 300 hours of exposure.

The major sign of intoxication in rabbits following an acute oral dose of 1.6–1.9 grams/kg of cyclohexanone was narcosis (Ref. 52).

Pathological examination also revealed marked lung damage, including atelectasis, edema, hemorrhage, and necrosis of the respiratory epithelium (Ref. 52). Treon *et al.* (1943a) also noted severe, widespread, vascular damage at unspecified dosage levels. Postmortem examination of rat and mice dosed with cyclohexanone revealed intestinal congestion, suggesting an irritant effect. Light narcosis and loss of coordination were also observed in rabbits given an inhalation dose of 3,082 ppm, 6 hours per day, 5 days per week, for 90 hours, but not in rabbits given 1,414 ppm for 300 hours, under the same dosing schedule (Ref. 53). Irritation to cyclohexanone was also observed down to 300 ppm but was not seen at the lowest dose of 190 ppm (total exposures for 300 hours).

Cyclohexanone has also been shown to be irritating to both the skin and eyes of rabbits (Refs. 8 and 19). Undiluted cyclohexanone (0.005 ml and 0.02 ml) applied directly to the eyes of rabbits caused injury of grade 5 (out of a maximum severity score of grade 10, which the authors classified as having a severe irritating effect (Ref. 8). Topical application of cyclohexanone to the skin of rabbits, as a 12.4 to 99 percent solution in cottonseed oil, caused slight (12.4%) to moderate (49.5%) to greater than marked (99%) skin irritation within one day of application (Ref. 19). The irritation effect seen from each solution gradually decreased, with no observable irritation on day 2, day 3, and day 7 for each of the above three concentrations, respectively.

3. *Subchronic and chronic toxicity.* The major effects seen from subchronic exposure to cyclohexanone include primary irritation and general central nervous system effects such as narcosis, lethargy, tumors, and hypothermia (Refs. 27 and 53).

Rengstorff *et al.* (1972) also observed a significant cataractogenic effect when cyclohexanone was administered to guinea pigs three times per week for 3 weeks, however, subsequent studies have not confirmed that cyclohexanone causes cataractogenic effects. In the Rengstorff *et al.* (1972) study, three groups of guinea pigs received cyclohexanone either cutaneously (0.5 ml doses of undiluted material) or subcutaneously (0.05 ml doses of 5 percent cyclohexanone in saline).

Subsequent work includes: studies sponsored by the Industrial Health Foundation (1983b) in which rats and guinea pigs were cutaneously administered cyclohexanone using the same dose and treatment schedule as Rongstorff *et al.*; studies by Travenol Laboratories (1982) in which rabbits and guinea pigs were administered cyclohexanone intravenously (iv) at two dosages (0.5 and 5.0 mg/kg), or cutaneously, at a dosage of 0.5 ml of undiluted cyclohexanone, again using the same treatment schedule as Rongstorff *et al.* (1972); and a study by Creener *et al.* (1982) in which rats were administered (iv) 50 and 100 mg/kg cyclohexanone in saline solutions containing 0.25 and 0.50 percent cyclohexanone, respectively, for 28 consecutive days. No cataractogenic effect due to cyclohexanone was observed in any of the three species tested in these studies. Additionally, data from the studies utilizing guinea pigs also indicated that guinea pigs are not an appropriate model for cataractogenesis studies; lenticular changes are indicated to be an inherent characteristic of guinea pigs, as shown by relatively high levels of cataracts observed in the control groups (Refs. 22, 51 and 55).

4. *Neurotoxocity.* Although cyclohexanone exhibits generalized CNS effects with sufficient administration, it does not appear to affect the peripheral nervous system. Perbellni *et al.* (1981) studied cyclohexanone in Sprague-Dawley rats to determine whether or not cyclohexanone causes peripheral nervous system lesions. Control rats were treated with peanut oil and experimental rats received intraperitoneally 400 mg/kg/day cyclohexanone. The animals were dosed for a 5 day period each week for 13 weeks. After 6 and 13 weeks of administration, electrophysiological and histological examinations were performed. The rats treated with cyclohexanone remained in good condition throughout the study and maintained a steady weight-gain comparable to the controls. The treated rats did not exhibit signs of neurotoxicity, such as motor deficits or ataxia, either at week 6 or week 13. The neuropathological examination also showed that there was no effect indicative or neurologic deficit.

5. *Mutagenicity.* The mutagenic potential of cyclohexanone is somewhat unclear. Masseud *et al.* (1980) obtained positive results in mutagenicity assays with *Bacillus subtilis* and *Salmonella typhimurium* (strains TA 1535, TA 1537, TA 1538, TA 98, and TA 100).

However, Florin *et al.* (1980) also ran cyclohexanone in the Ames assay (with and without metabolic activation) in *S. typhimurium* strains TA 1535, TA 1537, TA 98, and TA 100 and found negative results in their tests. Collins (1971) found that cyclohexahone also had a cytogenetic effect in his investigations using human leukocyte cultures. McGregor (1980) screened cyclohexanone for mutagenic effects in five tests: unscheduled DNA synthesis (UDS), bone marrow cytogenicity, mouse dominant lethal, sperm abnormality, and *Drosphila* sex-linked recessive lethal. The UDS and sperm abnormality tests appeared to be clearly negative; the three other tests were also considered by the author to be statistically negative, but the results were not as clear because of various problems with reproducibility, positive control response or, in one case, with the experimental response possibly being affected by a viral infection in the animals.

6. *Teratogenicity.* A study done on chicken embryos by Griggs *et al.* (1971) indicates that cyclohexanone may have teratogenic potential. Six experimental groups of eggs were exposed to cyclohexanone vapors (at an unknown, but reportedly constant concentration) for 3 to 12 hours, beginning at either the start of incubation or after the first 96 hours of incubation; there also were six nonexposed control groups. Although the results are difficult to interpret, there did appear to be treatment-related effects, such as increased mortality and, in two experimental groups, functional changes observed in the chicks. The chicks were unable to walk and had curled-in toes. There were no other anatomical abnormalities observed, aside from the curled toes. Griggs *et al.* (1971) postulated that an upper motor neuron lesion or other functional abnormality at the neuromuscular junction would be the embryopathic effect of cyclohexanone. No histopathology was performed, however.

7. *Reproductive effects.* There are no adequate reproductive effects studies of cyclohexanone. Hall *et al.* (1974) reported a study in which eight female CF_1 mice were dosed intraperitoneally for 28 days with 80 mg/kg/day cyclohexanone. Compared to control values, the experimental mice had the same percentage of pregancies and 83 percent as many viable fetuses per litter (a value of 75 percent would be considered significant in this test). The number of resorption sites was 46 percent of the control value of 0.46 per litter. A significant anti-fertility effect was, therefore, not observed for cyclohexanone in this screening test.

C. Environmental Fate and Effects Information

1. *Environmental fate.* Cyclohexanone is very water soluble (23,000 mg/l at 20°C), of moderate volatility (4 mm Hg at 20°C), with a low soil adsorption coefficient (Koc=17) and a low octanol/water partition coefficient of log P=0.81 (Refs. 12 and 56). As discussed in Unit II.A., most of the cyclohexanone released into the environment will be released to air. Most of this release will be from cyclohexanone's dispersive use as a solvent, and concentrations in air will be low. Low environmental concentrations are also expected as a result of wastewater discharge from manufacturing plants (see Unit II.A.). Data obtained from mathematical modelling indicate that cyclohexanone will partition preferentially to water from air. It will also volatilize from water 1 meter in depth to air with a calculated half-life of 2.6 to 5.0 days (Refs. 13 and 24). Modelling by Falco *et al.* (1980) further indicates that little cyclohexanone will be sorbed to soils or sediments and that concentrations in these compartments will only be a fraction of those in the water compartment (Ref. 15).

In air, cyclohexanone should readily break down by photo-oxidation or photolysis reactions (Refs. 3, 24 and 36). In urban atmosphere, cyclohexanone is expected to photodecompose at a fairly rapid rate, with a half-life of 1.9 to 3.2 hours (Ref. 24). In rural atmospheres, which have a low concentration of hydroxyl radicals and other oxidizing compounds, photodegradation would be much slower and would depend more strongly on cyclohexanone's potential for direct photolysis. Cyclohexanone is also expected to undergo direct photolysis. Serat and Mead (1959) reported that cyclohexanone absorbs substantial amounts of radiation at wavelengths above 290 nm (a cut-off value on the low end for photolysis, Ref. 34).

In water or soils, cyclohexanone is readily degraded by microorganisms. A number of microorganisms have been identified as being able to grow on and degrade cyclohexanone, including strains of *Nocardia Zoogloea*, *Acinetobacter*, and *Pseudomonas*. These species were isolated from soil, sewage and estuarine habitats and grew on and degraded cyclohexanone while using the chemical as a sole carbon source (Refs. 2, 11, 35, 38, 48, 49 and 50). Murray *et al.*

(1974) found that *Nocardia* sp. grew at an average rate of 0.22/hr. using cyclohexanone as a carbon source. There was an initial lag of 10 hours with the stationary phase of growth reached by 30 hours. Pitter (1976), found that an initial cyclohexanone concentration of 200 mg/liter disappeared, as measured by chemical oxygen demand (COD), from a medium of adapted activated sludge at a rate of 30 mg COD/g dry inoculum per hour over a 5 day period. Patel and Patel (1977), in another test, found that after 5 days 58.3 percent of theoretical oxygen demand for cyclohexanone was removed when cyclohexanone was added to acclimated sewage sludge from a laboratory-scale activated sludge unit. Measured COD in this experiment was 2.44 mg/mg; measured biological oxygen demand (BOD) was 1.0 g/mg; and theoretical oxygen demand was 2.74 mg/mg.

2. *Environmental effects.* Cyclohexanone has been shown to be only slightly toxic to a variety of organisms that have been tested in acute toxicity tests. Acute LC_{50} values for the fish, *Leuciscus idus*, and the invertebrate, *Daphnia magna*, were between 536 and 800 mg/L (Refs. 6 and 25).

Tests on algae, a protozoan, and terrestrial plants also indicate that cyclohexanone is not very toxic to environmental species. In toxicity tests of seven days duration with the algae *Scenedesmus quadricauta* and *Microcystis aeruginosa*, cyclohexanone inhibited cell multiplication at concentrations of 52 mg/L and 370 mg/L, respectively, (Ref. 7). In a similar test of three days duration, the minimum concentration for inhibition of cell multiplication for the protozoan, *Entosiphon sulcatum*, was 545 mg/L (Ref. 8). Corn plants irrigated with wastewater containing cyclohexanone were unaffected in terms of yields of cobs and number of kernels per cob, compared to untreated plants, up to the highest concentration tested, 500 mg/L (Ref. 10). Reynolds (1977), however, observed a 50 percent inhibition of seed germination of lettuce seeds at a cyclohexanone concentration of 41 mg/L.

III. Testing Program Proposed by Representatives of the Cyclohexanone Industry

In the spring of 1981, EPA began discussions with representatives of the cyclohexanone industry regarding the need for testing of cyclohexanone to characterize its health and environmental effects. The industry, organized as the Cyclohexanone Study Group under the auspices of the Industrial Health Foundation, submitted a testing proposal to address the EPA's testing concerns for the potential health effects of cyclohexanone. The study group was not asked to pursue environmental effects testing in the program because the Agency does not believe that environmental effects testing is necessary at this time. The Study Group was, however, asked to address all of the health effects concerns raised by the ITC, and their proposal includes testing for all of the ITC's and the Agency's effects of concern in this area.

Mutagenicity, teratogenicity, and reproductive effects testing will be performed by the Study Group. The neurological and behavioral effects on rats exposed prenatally to cyclohexanone will also be examined. Mutagenicity testing will examine the induction of sister chromatid exchanges, chromosome aberrations and gene mutations, using cultured Chinese hamster ovary cells. Protocols for the mutagenicity testing have been submitted by the Study Group and have been reviewed by the Agency and judged to be adequate. The Study Group has proposed that mutagenicity testing begin September 28, 1983, be completed December 15, 1983; with a final report on April 30, 1984. Teratogenicity testing will be an inhalation study using the rat. A probe study, setting exposure concentrations, has already been completed. Both the teratogenicity protocol and the probe study have been reviewed and found adequate by the Agency. The Study Group will also run, in tandem with the rat teratogenicity study, a teratogenicity screening study using the mouse. Mice will be exposed to cyclohexanone at the high dose of the rat study, using a sufficient number of mice to obtain 20 pregnant females. The effects of cyclohexanone on these mice will be compared to a control group. Should a teratogenic effect be seen, a full teratogenicity study on mice will be conducted by the Study Group. The Study Group proposed that the teratology study begin October 15, 1983, and be completed December 15, 1983; with a final report on April 30, 1984.

The protocol for the reproductive effects test has been received by the Agency and testing is anticipated to start in 1984. Included as an addition to the reproductive effects study is a study to examine development neuropathology in the rat. Previous work by Perbellini *et al.* (1981) demonstrated no neurological effects on adult rats; however, work by Griggs *et al.* (1971) on chick embryos did show effects on developing chickens and suggested a need for follow-up work using mammals. The Study Group has proposed test initiation two months after final EPA publication in the Federal Register accepting the Study Group's test program; with test completion 13 months after test initiation, and a final report 24 months after test initiation.

The Study Group has furnished EPA with the names and addresses of the laboratories conducting these tests. The Study Group has also committed to adhere to the final TSCA Good Laboratory Practice Regulations.

The Study Group also has agreed to permit laboratory audits/inspections in accordance with the authority and procedures outlined in TSCA, section 11, at the request of duly designated representatives of the EPA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluation thereof, and that the studies are being conducted according to Good Laboratory Practices.

The Study Group has further committed that all raw data, documentation, including correspondence related to the conduct and interpretation of the study, records, protocols, specimens, and reports generated as a result of each study will be retained for 10 years. In addition, the raw data documentation, records, protocols, specimens, and reports, will be made available during an inspection or submitted to EPA if requested by EPA or its duly designated representative.

The Agency plans to issue in the Federal Register a notice of the receipt of all data submitted under this test program. Subject to TSCA section 14, the notice will provide information similar to that described in section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Should the Study Group fail to conduct the testing according to the specified protocols or fail to follow Good Laboratory Practices, such actions may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule or otherwise require further testing.

IV. Decision Not To Initiate Rulemaking

The Agency has concluded that there are sufficient data on cyclohexanone's environmental release, fate, and effects to indicate that, at the present time, cyclohexanone does not present an unreasonable risk to the environment. In addition, while the quantity of

cyclohexanone released to the environment might be considered substantial as that term is used in TSCA section 4(a)(1)(B)(i), EPA believes that available data allow the Agency to reasonably predict that the effects on the environment of such releases will be minimal. Cyclohexanone is readily degraded in the environment and data indicate that cyclohexanone is only slightly toxic to environmental organisms (see Unit II.C.). Furthermore environment levels of cyclohexanone in air, water, and soils are expected to generally be much less than 1 ppm (see Unit II.A.). Therefore, the Agency is not at this time requiring testing of this substance for environmental fate or effects under section 4 of TSCA.

The Agency further believes that the results of the testing being undertaken by the Study Group, combined with exising data, are likely to provide sufficient data to reasonably determine or predict the health effects of cyclohexanone for which EPA has concluded testing should be undertaken. EPA, therefore, is not proposing a TSCA section 4 rule for health effects testing at this time. The Study Group has agreed to test for mutagenicity, teratogenicity, reproductive effects, and developmental neuropathology. Cataractogenic effects of cyclohexanone have already been examined to the Agency's satisfaction, and a 2-year oncogenicity study has been performed by the National Cancer Institute. The National Toxicology Program is now evaluating the data and has not yet released results. The ITC also recommended epidemiology studies. However, the Agency has concluded that an epidemiology study is not practical at this time. There has not yet been identified a cause-effect relationship for an effect of cyclohexanone in laboratory animals that is of sufficient significance or distinction that one could reasonably pursue in epidemiology study for this substance. The Agency will, however, reevaluate the need for an epidemiology study when the results of the Study Group's program are received.

In conclusion, the Agency has decided not to initiate rulemaking to require further testing of cyclohexanone at this time. However, should the test results from the Study Group or other information reveal a need for additional testing that the Study Group is unwilling to perform, the Agency reserves its right to require testing under section 4(a).

EPA is soliciting comments on the IHF Cyclohexanone Study Group's program and the Agency's decision to accept it in lieu of section 4(a) rulemaking at this time. After considering these comments, EPA will either publish in the Federal Register a final notice of acceptance of a negotiated test program or will initiate rulemaking under section 4(a) of TSCA.

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VI. Public Record

The EPA has established a public record for this testing decision, docket number [OPTS–42046] which includes:

(1) Federal Register notice designating cyclohexanone to the Priority list and comments received thereon.

(2) Communications from industry consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E–107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: December 21, 1983.

William D. Ruckelshaus,

Administrator.

[FR Doc. 83-34801 Filed 12-30-83; 8:45 am]

BILLING CODE 6560-50-M

[OPTS–53056; FRL 2500–6]

Premanufacture Notices; Monthly Status Report for November 1983

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(d)(3) of the Toxic Substances Control Act (TSCA) requires EPA to issue a list in the Federal Register each month reporting the premanufacture notices (PMNs) pending before the Agency and the PMNs for which the review period has expired since publication of the last monthly summary. This is the report for November 1983.

DATE: Written comments are due no later than 30 days before the applicable notice review period ends on the specific chemical substance. Nonconfidential portions of the PMNs may be seen in Rm. E–106 at the address below between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

ADDRESS: Written comments are to be identified with the document control number "[OPTS–53056]" and the specific PMN number should be sent to: Document Control Officer (TS–793), Information Management Division, Office of Toxic Substances, Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–409, 401 M Street, SW., Washington, D.C. 20460, (202–382–3532).

FOR FURTHER INFORMATION CONTACT: Wendy Cleland-Hammett, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Rm. E–220, 401 M Street, SW., Washington, D.C. 20460. (202–382–3706).

SUPPLEMENTARY INFORMATION: The monthly status report published in the Federal Register as required under section 5(d)3) of TSCA (90 Stat. 2012 (15 U.S.C. 2504)), will identify: (a) PMNs received during November; (b) PMNs